



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/525,644

03/17/2005

Takeshi Ito

28361U

8336

20529

7590

03/12/2010

THE NATH LAW GROUP

112 South West Street

Alexandria, VA 22314

EXAMINER

MERCIER, MELISSA S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

03/12/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,644	<b>Applicant(s)</b> ITO ET AL.	
	<b>Examiner</b> MELISSA S. MERCIER	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-21-09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicants Remarks and Amended Claims filed on November 17, 2009 is acknowledged. Claims 1-3 and 8-10 remain pending in this application.

### ***Information Disclosure Statement***

Receipt of the Information Disclosure Statement filed on August 21, 2009 is acknowledged. A signed copy is attached to this office action.

### ***Withdrawn Rejections/Objections***

#### ***Claim Rejections - 35 USC § 103***

The rejection of claims 1-3 and 8-10 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (EP 1 201 232) in view of Applicants amendment to the claims to recite 1-5% by weight of the copolymer of 2-ethylhexyl acrylate and vinyl acetate monomers in the adhesive layer.

The rejection of claims 1-3 and 8-10 under 35 U.S.C. 103(a) as being unpatentable over Mantelle et al. (US Patent 6,210,705) in view of Sablotsky (US Patent 4,994,267) and further in view of Gale (US Patent 5,614,211) in view of Applicants amendment to the claims to recite 1-5% by weight of the copolymer of 2-ethylhexyl acrylate and vinyl acetate monomers in the adhesive layer.

### ***Maintained Rejections***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, and 8-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 8, 9-11, and 13-14 of copending Application No. 10/469,612. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a patch comprising a backing layer or a support (which are identical), a drug, an adhesive layer comprising identical acrylic polymers and styrene copolymers, and a tackifier. The subject matter covered in either patent would cover the subject matter of the other.

Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only

Art Unit: 1615

routine skill in the art. In re Aller, 105 USPQ 233. The only difference between the two sets of claims is the recitation of a specific weight ratio of acrylic polymer to styrene polymer, however, It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant has argued that the claims in the '612 application do not recite the weight percents and ratio of the acrylic polymer to the styrene polymer and is thus patentably distinct from the instant claims. The Examiner respectfully disagrees. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug. Furthermore, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Applicant has not presented any arguments or evidence to indicate that the ratio is not easily optimizable through routine experimentation.

### ***Newly Applied Rejections***

***Claim Rejections - 35 USC § 103***

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houze et al. (US 2002/0058068) in view of Sablotsky (US Patent 4,994,267) and further in view of Gale (US Paten 5,614,211).

Houze discloses dermal compositions for administration of a drug comprising a blend of two or more acrylic-based polymers having differing functionalities (abstract). The polymer matrix is disclosed as being a pressure sensitive adhesive for direct attachment to the user's skin (paragraph 0023). The dermal composition also comprises a backing layer (paragraph 0103-0105).

Duro-Tak ® 87-2097, which is the instantly claimed acrylate-vinylacetate copolymer is disclosed as suitable for use. See examples for preparations comprising 2.6% of the copolymer (Examples 17 and 20). Houze further discloses other natural or synthetic polymers can be included in the adhesive, including rubbers (paragraph 0055).

Houze does not disclose the particular styrene polymer or an explicit disclosure of a formulation comprising an acrylic polymer and a rubber based polymer

Sablotsky discloses a dermal composition comprising a drug, an acrylate polymer, a rubber polymer and a tackifying agent (column 4, lines 12-14). Sablotsky teaches styrene-isoprene-styrene block copolymers may be used in the composition (column 5, lines 34-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the styrene copolymer of Sablotsky in the

Art Unit: 1615

composition of Houze in order to provide a transdermal application in order to modulate the drug solubility in the polymer matrix and the delivery rate of the drug.

The combination of Houze and Sablotsky does not disclose the use of oxybutynin as a drug.

Gale discloses the use of oxybutynin for transdermal delivery.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated oxybutynin as an active agent in transdermal delivery device as disclosed by Houze and Sablotsky since it is known to be routinely administered transdermally as evidenced by Gale.

The cited references fail to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:4 to 1:19. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be 1:4. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1615

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1615